

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

PATRICIA S. PEREZ, individually and on behalf of
her minor child I.R.,

Plaintiff,

-against-

NEW YORK STATE DEPARTMENT OF HEALTH
and HOWARD A. ZUCKER, in his official capacity
as the Commissioner of New York State Department
of Health,

Defendants.

Case No. 1:21-CV-1203 (GTS/CFH)

COMPLAINT

Plaintiff, by and through her undersigned counsel, alleges on personal knowledge as to herself and upon information and belief as to all other matters:

PRELIMINARY STATEMENT

1. Plaintiff is fully vaccinated and has also received the COVID-19 vaccine. Plaintiff's child, I.R., is a 10th grade student and is also fully vaccinated and has received all vaccines required under New York law to attend school with the exception of one dose of Tdap (tetanus toxoid, diphtheria toxoid, and reduced acellular pertussis vaccine) and a dose of IPV (inactivated polio vaccine). Plaintiff has made an informed parental decision to not administer these doses because, *inter alia*: her child is already immune to tetanus, diphtheria, pertussis and polio; these vaccines, unlike others, do not prevent infection and transmission of these pathogens; and while these products have known risks, and a heightened risk for I.R. based on her medical history, there is no personal or communal benefit to giving these products to I.R. Nevertheless, Defendants are overriding Plaintiff's parental decision and forcing I.R. to be injected with Tdap and IPV in order to attend school.

2. Conditioning the provision of a government benefit, such as school where I.R. receives much needed disability services, on the injection of these products, and overriding a parent's informed decision, impinges upon Plaintiff's and her child's fundamental rights, including parental choice, bodily integrity, and informed consent. To impinge on these rights, Defendants must demonstrate a compelling state interest that is implemented in the least restrictive means possible.

3. Courts have previously recognized that New York's desire to control the spread of infectious diseases can create a compelling state interest. Those courts have then balanced the individual's rights regarding their own medical care against the state's compelling interest and concluded that the state's interests outweigh the individual's interest. However, because the vaccine products at issue in this case do not prevent transmission of the infections, the compelling state interest to control infection from person to person does not apply in this case.

4. The pertussis vaccine cannot form the basis of a compelling interest to control infection because it does not prevent a vaccinated person from becoming infected or transmitting pertussis. For example, sixteen scientists and professors, considered world-leading experts in pertussis, participated in a Consensus Conference regarding pertussis vaccines organized by the World Association for Infectious Disease and Immunological Disorders on June 22, 2018. These scientists and professors, along with this association, published a peer reviewed publication explaining, in relevant part, that:

aPVs [acellular pertussis vaccines] ... can prevent disease **but cannot avoid infection and transmission.** ...

aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of *B. pertussis* and do not exert any herd immunity effect.

Frontiers in Immunology, *Pertussis Prevention: Reasons for Resurgence, and Differences in the Current Acellular Pertussis Vaccines* (2019) (emphasis added). *See also* Vaccine, *Will we have new pertussis vaccines?* (2018) (“neither DTP, nor DTaP or Tdap prevent asymptomatic infection and silent transmission of the [pertussis] pathogen”). Pertussis vaccines also render those who are vaccinated susceptible to becoming repeatedly infected with pertussis. Given that the pertussis vaccine does not prevent infection and transmission, conditioning a government benefit on the injection of this product into Plaintiff’s child over her objections in order to prevent transmission of pertussis is an unjustifiable infringement on their constitutional rights. (*Infra* Count I.)

5. The compelling state interest to prevent transmission of an infection is also absent with regard to vaccination for diphtheria. The diphtheria vaccine does not prevent infection nor does it stop transmission of the infection to others. Instead, the vaccine is only designed to create antibodies to a toxin sometimes released by the diphtheria bacteria that can cause the symptoms associated with the infection. *See, e.g., American Journal of Diseases of Children, Diphtheria immunization. Effect upon carriers and the control of outbreaks* (1972) (“Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection.”) Since the diphtheria vaccine does not prevent infection and transmission, conditioning a government benefit on the injection of this product into Plaintiff’s child over her objections in order to prevent transmission of diphtheria is an unjustifiable infringement on their constitutional rights. (*Infra* Count II.)

6. The compelling state interest to prevent transmission of an infection is also absent with regard to vaccination for tetanus because tetanus is not contagious from person-to-person. *See, e.g., CDC, Epidemiology and Prevention of Vaccine-Preventable Disease* (“Tetanus is not contagious from person to person.”) Since tetanus is not transmissible from person to person,

conditioning a government benefit on the injection of a tetanus vaccine into Plaintiff's child over her objections in order to prevent transmission of tetanus is an unjustifiable infringement on their constitutional rights. (*Infra* Count III.)

7. The compelling state interest to prevent transmission of an infection is also absent with regard to the inactivated polio vaccine ("IPV"). This polio vaccine is not the one developed by Jonas Salk nor is it the Sabin polio vaccine, but rather it is a novel Sanofi product licensed in 1990. IPV has been the exclusive polio vaccine used in the United States since approximately the year 2000. IPV does not prevent the recipient from becoming infected with the polio virus nor does it stop an infected person from transmitting the virus to others. Instead, IPV only prevents a person injected with this vaccine from developing potential complications from the polio virus. *See* WHO, UNICEF, CDC, Polio Global Eradication Initiative, *Inactivated poliovirus vaccine* ("IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces ... IPV does not stop transmission of the virus."). Since IPV does not prevent infection and transmission, conditioning a government benefit on the injection of this product into Plaintiff's child over her objections in order to prevent transmission of polio is an unjustifiable infringement on their constitutional rights. (*Infra* Count IV.)

8. Even if these vaccines could prevent infection and transmission, which is not the case, **Plaintiff's child already has immunity to all of the pathogens to which these vaccines are intended to create immunity. Her antibody levels for each pathogen exceeds the antibody levels deemed to confer immunity in the clinical trials relied upon to license these products.** (*Infra* Counts I - IV.)

9. On the other hand, these products are not without risk. It is a well-established and indisputable fact, confirmed by the FDA, CDC, and vaccine manufacturers, that these products can, for some children, cause serious injury and death. (*Infra* Count V.) The potential harm from these products is also confirmed by their pre-licensure clinical trials, and the over one hundred serious adverse effects identified by their manufacturers post-licensure because the manufacturers had a basis to believe there is a *causal* relationship between these injuries and their pertussis products. (*Id.*) The harm caused by pertussis vaccine was, for example, the primary reason Congress passed the National Childhood Vaccine Injury Act of 1986 (the “**1986 Act**”) which granted pharmaceutical companies’ immunity from liability for injuries caused by their vaccine products. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011) (“[B]y the mid-1980’s ... the remaining manufacturer [of diphtheria, tetanus and pertussis vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200.”).

10. Despite the foregoing, Defendants require that Plaintiff, “shall have administered to” her child additional doses of vaccines that only offer personal protection, not communal protection, and are for pathogens to which **she is already immune**. If she does not do so, Defendants will require that Plaintiff’s child is excluded from receiving a governmental benefit and from school.

11. For these reasons, and those discussed below, Plaintiff respectfully seeks to enjoin Defendants from enforcing Public Health Law Section 2164, to the extent it conditions a government benefit on the receipt of Tdap and IPV. Plaintiff also respectfully seeks declaratory relief regarding the legality and constitutionality of this requirement facially and as applied to Plaintiff and her child.

PARTIES

12. Plaintiff Patricia Perez is the mother of I.R. She graduated from Cornell University with a B.S. in Environmental/Organizational Psychology and worked as a research assistant in the biology department at Cornell. Ms. Perez also participated in a program that allowed her to shadow an infectious disease doctor treating AIDS patients at Weil Cornell Medical in the early nineties, volunteered as an outreach educator while at Cornell to prevent AIDS transmission, and studied epidemiology at UCLA. Ms. Perez also obtained her Juris Doctor and has worked as an attorney for Paul Weiss Rifkind, Wharton and Garrison, and Sobo & Sobo. She now works as an attorney at a public interest law group in the Hudson Valley.

13. Defendant Howard A. Zucker, in his official capacity, is the Commissioner (“**Commissioner**”) of the New York State Department of Health (“**NYSDOH**”) (collectively, “**Defendants**”) who enforce the law which excluded I.R. from attending school where she receives services and attending school because she is missing a dose of Tdap and IPV.

14. Letitia James, in her capacity as the New York State Attorney General, was provided notice of this action.

BACKGROUND

15. New York Public Health Law Section 2164 provides, *inter alia*, that:

Every person in parental relation to a child in this state shall have administered to such child an adequate dose or doses of an immunizing agent against poliomyelitis, mumps, measles, diphtheria, rubella, Haemophilus influenzae type b (Hib), hepatitis B and varicella ...

...

No principal ... of a school shall permit any child to be admitted to such school, or to attend such school ... without ... evidence of the child’s immunization against poliomyelitis, ... diphtheria, ... pertussis, tetanus...

16. The only licensed and available vaccines to meet the diphtheria, pertussis, and tetanus requirement are sold by GSK and Sanofi and are sold under different trade names and combinations. The brands given to children under six years of age are known as DTaP, and for those older than six years, Tdap. Since 2000, Sanofi sells the only licensed polio vaccine used in the United States – IPV, licensed in 1990, eleven years after the last wild case of polio in the United States. This is *not* the polio vaccine created by Jonas Salk or Albert Sabin. It is very different as Sanofi makes clear in IPV’s package insert, and as further described below. Defendants are denying I.R. government benefits, namely disability services provided through schooling, unless Plaintiff has a dose of Tdap and IPV injected into I.R.

17. When Plaintiff gave birth to I.R. she was a healthy baby, who smiled for the first time at 1 month old. However, as time progressed, I.R. suffered various auto-immune dysfunctions. She presented with many allergy symptoms such as blotchy skin, folds under her eyes, and she scratched incessantly. I.R. also had an inability to tan, has shiners under I.R.’s eyes, pallor, eczema flare ups, and absence of any illnesses. Furthermore, I.R. has abnormally high elevated antibodies to various pathogens for which she has been vaccinated, such as her antibodies for pertussis and mumps, indicating an overly aggressive immune response to prior vaccination for these pathogens. As early as 18 months, I.R. exhibited central nervous system dysfunction. I.R. now lives with and is treated for diagnostic code 299, or “other nervous system disorder.” Plaintiff avoids stimuli that may further disrupt I.R.’s immune or central nervous system.

18. I.R.’s medical condition, however, does not qualify her for a medical exemption to Tdap or IPV, which is effectively limited to children that are severely immunocompromised or who have had anaphylaxis (life threatening allergic reaction) or encephalopathy (brain damage) from a prior dose of that same vaccine. See <https://www.cdc.gov/vaccines/hcp/acip-recs/general->

[recs/contraindications.html](#). Therefore, Plaintiff has been unable to obtain a medical exemption from I.R.'s doctors.

19. Because I.R. is missing a dose of Tdap and a dose of IPV, Defendant has excluded her from school and the disability services provided therein. I.R. is suffering without being able to attend school where she was previously able to be with peers with similar medical conditions to her condition, as well as peers without such a disorder. I.R. thrived at, and enjoyed school, especially socializing with other children.

20. I.R. now has no contact with typical peers or those with similar conditions. Her prior placement was a classroom where there were up to five peers with similar medical conditions and three teachers, all within a typical school. This was meaningful in that she was able to interact with typical peers. I.R. would call out to people in the hallways and say hello or strike up conversations. Now, instead, she spends almost all her time without any peers.

21. I.R. also previously participated on the school track team, an activity she sorely misses. She is now not able to run track or engage in other favored school activities which she previously did. I.R. is also no longer able to participate in or experience school assemblies, concerts, gym classes, lunch time, or special events. She is also missing out on a special classroom environment with teachers and curricula geared towards her needs.

COUNT I

42 U.S.C. § 1983

Violation of the Fourteenth Amendment

Conditioning a Public Benefit on the Injection of aPV

Parental Choice, Bodily Integrity, Informed Consent, and Life and Liberty

22. The preceding paragraphs are hereby realleged and incorporated herein by reference.

23. Plaintiff is fully competent and able to make decisions based on the best interests of I.R. Informed consent requires that an individual be informed of the risks and benefits of a

medical procedure and then be provided the uncoerced discretion to decide whether to consent to the medical procedure. Plaintiff opposes injecting I.R. with pertussis vaccine when, *inter alia*, **there is only risk and no benefit to engaging in this medical procedure because I.R. is already immune to pertussis and this product only affords personal and not communal protection.**

24. The United States Constitution guarantees the fundamental right to parental choice, including medical choice; the fundamental right to bodily integrity; the fundamental right to informed consent prior to administering a medical procedure; and the substantive due process rights to liberty and to life. None of these fundamental rights can be infringed upon without a compelling state interest that is implemented in the least restrictive means.

25. New York Public Health Law Section 2164(2)(a) requires that “Every person in parental relation to a child in this state shall have administered to such child an adequate dose or doses of an immunizing agent against ... pertussis.” New York Public Health Law Section 2164(7) further provides that “No principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school, or to attend such school ... without ... acceptable evidence of the child’s immunization against ... pertussis.” This requirement is repeated in 10 NYCRR § 66-1.1(f).

26. Prior court decisions have found that a compelling state interest to control the spread of infection can trump certain constitutional rights in certain situations. This compelling state interest is absent with regard to vaccination for pertussis since this vaccine does not prevent the vaccinated from becoming infected and transmitting pertussis.

27. It is established, including by researchers at the FDA and premier universities, that pertussis vaccines may decrease the odds of a person experiencing the symptoms of pertussis, but these products create a defective form of immunity to pertussis that does not prevent infection and

transmission. This defective immunity actually causes vaccinated individuals to become repeatedly infected with pertussis, potentially every month, without knowing they are infected. As noted above, sixteen scientists and professors considered world leading experts in pertussis, participated in a Consensus Conference organized by the World Association for Infectious Disease and Immunological Disorders on June 22, 2018, regarding the pertussis vaccine and concluded in a peer reviewed publication that:

Natural infection evokes both mucosal and systemic immune responses, while aPVs induce only a systemic immune response. ... Mucosal immunity is essential to prevent colonization and transmission of B. pertussis organisms. Consequently, preventive measures such as aPVs that do not induce a valid mucosal response can prevent disease but cannot avoid infection and transmission.

...

aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. pertussis and do not exert any herd immunity effect.

This peer reviewed publication similarly explained in its conclusion that “[l]ack of mucosal immune responses after aPV [acellular pertussis vaccines] administration favor infection, persistent colonization, and transmission of the pathogen.”

28. Pertussis vaccines only afford personal protection by reducing the symptoms of pertussis but do not prevent transmission of the pertussis bacterium and do not exert any herd immunity effect.

29. In fact, the form of immunity created by the pertussis vaccine renders those vaccinated susceptible to becoming repeatedly infected with pertussis bacteria while not presenting symptoms. In other words, those vaccinated for pertussis can repeatedly become infected and are capable of silently transmitting pertussis while presenting no or few symptoms. On the other hand, the student that is not vaccinated for pertussis may become infected with pertussis bacteria once,

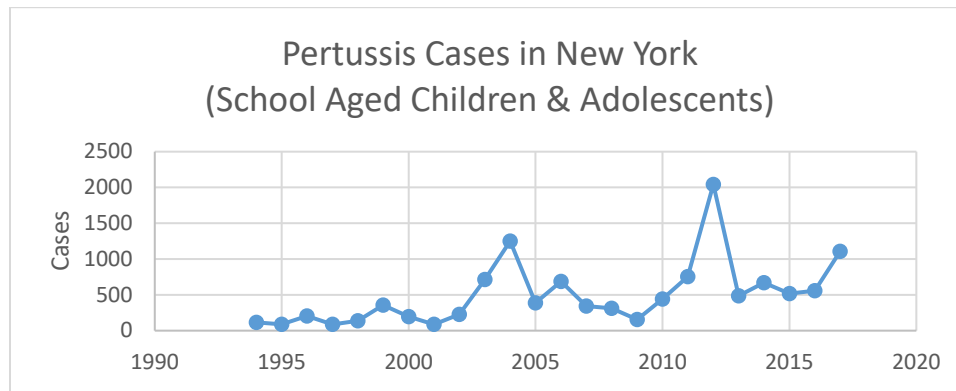
will have symptoms and know to isolate and not transmit, and for many years thereafter will have immunity that prevents the student from becoming re-infected and transmitting pertussis.

30. Science has also provided an explanation for why pertussis vaccine render those receiving this product repeat, asymptomatic carriers. Pertussis vaccines are designed to force the body to generate antibodies to antigens secreted by or found on the surface of the pertussis bacteria. The pertussis bacteria are estimated to have thousands of antigens on its surface or secreted proteins. All pertussis containing vaccines used in the United States contain only 5 of these antigens, and hence can only generate antibodies to 5 of the pertussis bacteria antigens. By generating antibodies to only 5 of the thousands of pertussis bacteria antigens, the result is that the vaccinated person may have few or no symptoms if infected with pertussis but will still become colonized with and silently transmit pertussis. This defective immunity is known as “linked epitope suppression” and remains even after an individual vaccinated for pertussis becomes infected with pertussis. The body of a pertussis-vaccinated individual will continue to generate a vigorous immune response to only the 5 antigens included in the pertussis vaccine, but not to other pertussis antigens, irrespective of how many times they become infected with pertussis. This renders individuals vaccinated for pertussis susceptible to repeatedly becoming infected with pertussis bacteria, potentially every few weeks for the rest of their life.

31. That vaccination for pertussis increases the circulation of this bacteria is confirmed by the fact that the time periods between pertussis outbreaks in the United States have become shorter, despite increased vaccinations. Had the amount of circulating pertussis bacteria gone down, the intervals between outbreaks would have gotten longer, but that has not occurred.

32. In fact, according to data published by the NYSDOH, available from 1994 to 2017, the number of clinical cases of pertussis among school-aged children in New York actually

increased after pertussis vaccine was first required to attend school in New York in 2007 for 6th graders and in 2011 for kindergarteners, (L 2004, ch 207; L 2006, ch 506):



See <https://www.health.ny.gov/statistics/diseases/communicable/>.

33. I.R. is also already immune to pertussis. Pertussis vaccines are licensed based on whether they generate a certain level of antibodies to pertussis. I.R.’s antibodies levels far exceed the level deemed to confer immunity as needed for licensure of pertussis vaccines.

34. Pertussis vaccine is also not without risk¹, yet Defendants demand that Plaintiff ignores these risks under penalty of being denied a critical government benefit even though there is no benefit to I.R. in engaging in this medical procedure.

¹ In the early 1980s there were only three routine childhood vaccines, one of which was a diphtheria, tetanus, and pertussis vaccine, and another which was a polio vaccine, and the financial liability for injury claims from these vaccines were many factors greater than the substantial revenue they generated. See *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 226 (2011) (“[B]y the mid-1980’s ... the remaining manufacturer [of diphtheria, tetanus and pertussis vaccine] estimated that its potential tort liability exceeded its annual sales by a factor of 200.”). In response, Congress passed the National Childhood Vaccine Injury Act of 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”) which virtually eliminated financial liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 ... against a vaccine ... manufacturer ... for damages arising from a vaccine-related injury or death.”); *Wyeth*, 562 U.S. at 243 (The 1986 “Act pre-empts all design-defect claims against vaccine manufacturers.”). Congress instead made the U.S. Department of Health and Human Services (“**HHS**”) responsible for vaccine safety, and created the Vaccine Injury Compensation Program (“**Vaccine Court**”), part of the U.S. Court of Federal Claims. See 42 U.S.C. § 300aa-1 *et seq.* The goal of this safety program is to reduce vaccine injuries. Nonetheless, as the respondent in Vaccine Court, HHS has paid over \$500,000,000 for injuries caused by just pertussis-containing vaccine despite a statutory cap of \$250,000 for death, and for pain and suffering, and vigorously defending, with DOJ as its counsel, against any claim of vaccine injury. *Id.* Petitioners also have no discovery as of right which is only granted “in rare and exceptional cases” and must almost always prove causation despite the fact that medical science is “a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). This is because unlike most drugs, the clinical trials relied upon to license Tdap and IPV did *not* have a placebo-control group, had small sample

35. Given the foregoing, conditioning government benefits of school and the provided disability services as a means to compel Plaintiff to inject I.R. with a pertussis vaccine she does not need does not pass strict scrutiny.

36. Even under the rational basis test, there is no rational basis to condition a government benefit on injecting a pertussis vaccine because those receiving the vaccine are more likely to spread the pertussis bacteria. Furthermore, as applied in this instance I.R. is immune to pertussis, and therefore the state has no rational basis to require she receive additional protection from the disease.

37. Conditioning a government benefit upon the injection of a pertussis vaccine therefore infringes upon the liberty rights to parental choice, bodily integrity, and informed consent prior to administering a medical procedure, and the substantive due process rights to liberty and to life.

38. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f), which require administration of vaccines and condition a government benefit of attending school and receiving special education services upon injection of pertussis vaccine that offers personal, not communal protection, and causes a defective form of immunity that renders the recipient more likely to spread

sizes, and the safety review periods are often days or weeks. <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states>. After licensure, as required by federal law, vaccine manufacturers are to include in the package insert for each vaccine “*only* those adverse events for which there is some basis to believe there is a *causal* relationship between the drug and the occurrence of the adverse event.” 21 C.F.R. § 201.57(c)(7) (emphasis added). Pursuant to this regulation, the inserts for DTaP/Tdap and IPV include over one hundred serious immune, neurological and other chronic adverse events/conditions.¹ The Institute of Medicine (“IOM”) has acknowledged that each child is different and the assessment of whether a child, such as I.R., should receive a vaccine, must be done on an individual basis. As the IOM explained in 2012: “Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact” but that “much work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients.” <https://www.nap.edu/read/13164/chapter/5#82>.

pertussis, should facially and as applied, be struck down for violating the foregoing fundamental rights arising from the Fourteenth Amendment of the United States Constitution.

COUNT II
42 U.S.C. § 1983

Violation of the Fourteenth Amendment
Conditioning a Public Benefit on the Injection of Tetanus Vaccine
Parental Choice, Bodily Integrity, Informed Consent, and Life and Liberty

39. The preceding paragraphs are hereby realleged and incorporated herein by reference.

40. Plaintiff opposes injecting I.R. with tetanus vaccine when, *inter alia*, there is only risk and no benefit to engaging in this medical procedure because I.R. is already immune to tetanus and this product only affords personal and not communal protection.

41. New York Public Health Law Section 2164(2)(a) requires that children receive “an adequate dose or doses of an immunizing agent against ... tetanus.”

42. The compelling state interest to control the spread of infection is absent with regard to vaccination for tetanus since this bacterium is not transmissible from person-to-person. *See, e.g.,* <https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html> (“Tetanus is not contagious from person to person.”) A person with tetanus cannot spread tetanus to another person.

43. Because tetanus is not contagious from person-to-person, I.R. cannot contract or transmit tetanus from or to another person. Tetanus vaccine does not prevent infection or transmission of tetanus from person-to-person of tetanus since tetanus is not contagious from person-to-person. Neither a person with current tetanus vaccination nor a person without any tetanus vaccine can infect another person with tetanus. I.R. cannot contract or transmit tetanus to anyone because tetanus is not contagious from person-to-person.

44. In any event, according to data published by the NYSDOH, available from 1994 to 2017, the number of cases of tetanus among school-aged children in New York was effectively

zero before and after tetanus vaccine was first required to attend school in New York in 2007 for 6th graders and in 2011 for kindergarteners. (L 2004, ch 207; L 2006, ch 506). In total, there were zero cases in all years between 1994 and 2017 with the exception of one case in in 2004, 2005 and 2012 and two cases in 2013. See <https://www.health.ny.gov/statistics/diseases/communicable/>.

45. I.R. is also already immune to tetanus. Tetanus vaccines are licensed based on whether they generate a certain level of antibodies to tetanus. I.R.'s antibodies levels far exceed the level deemed to confer immunity for licensure of tetanus vaccines.

46. Tetanus vaccine is also not without risk, yet Defendants demand that Plaintiff ignore these risks, under penalty of being denied a critical government benefit, even though there is no benefit to I.R. in engaging in this medical procedure.

47. Hence, compelling the injection of tetanus vaccine into I.R., against her mother's informed decision and under duress of denying a critical government benefit, including special education services, does not pass strict scrutiny.

48. Even under the rational basis test, there is no rational basis to condition a government benefit on injecting a tetanus vaccine because those vaccinated with the vaccine are no less likely to spread tetanus because tetanus is not contagious from person-to-person. Furthermore, as applied in this instance I.R. is immune to tetanus, and therefore the state has no rational basis to require she receive additional protection from the disease.

49. Expelling a child from school is also not the least restrictive means because I.R. is already immune to tetanus and because there were effectively no cases among school-aged children in New York before requiring tetanus vaccine to attend school in New York State, making it clear that preventing tetanus among school-aged children had already been achieved without needing to expel students in New York State from school for not receiving this product.

50. Conditioning a government benefit upon the injection of a tetanus vaccine therefore infringes upon the liberty rights to parental choice, bodily integrity, and informed consent prior to administering a medical procedure, and the substantive due process rights to liberty and to life.

51. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f), which require administration of vaccines and condition a government benefit of attending school and receiving special education services upon injection of tetanus vaccine that offers personal, not communal protection, should be facially and as applied, struck down for violating the foregoing fundamental rights arising from the Fourteenth Amendment of the United States Constitution.

COUNT III
42 U.S.C. § 1983

Violation of the Fourteenth Amendment
Conditioning a Public Benefit on the Injection of Diphtheria Vaccine
Parental Choice, Bodily Integrity, Informed Consent, and Life and Liberty

52. The preceding paragraphs are hereby realleged and incorporated herein by reference.

53. Plaintiff opposes injecting I.R. with diphtheria vaccine when, *inter alia*, there is only risk and no benefit to engaging in this medical procedure because I.R. is already immune to diphtheria and this product only affords personal and not communal protection.

54. New York Public Health Law Section 2164(2)(a) requires that every child receive “an adequate dose or doses of an immunizing agent against ... diphtheria.”

55. The compelling state interest to control the spread of infection is absent with regard to vaccination for diphtheria since this vaccine does not prevent person-to-person transmission of diphtheria because it only creates antibodies to a toxin released by the diphtheria bacteria, but does not generate any antibodies to the diphtheria bacteria itself. *See, e.g., American Journal of Diseases of Children, Diphtheria immunization. Effect upon carriers and the control of outbreaks*

(1972) (“Diphtheria toxoid helps prevent symptomatic disease but does not prevent the carrier state nor stop the spread of infection.”).

56. The diphtheria bacteria can sometimes cause clinical symptoms when it releases a particular toxin. The diphtheria vaccine contains a modified form of this toxin. The diphtheria vaccine does not contain any portion of the diphtheria bacteria itself. This vaccine therefore does not generate any antibodies that would target the diphtheria bacteria. It only generates antibodies against a toxin sometimes released by these bacteria. The diphtheria vaccine therefore does not prevent carriage and transmission of the diphtheria bacteria from person-to-person. *Id.* (“[T]here is no difference in the risk of diphtheria acquisition among those with full, lapsed, inadequate, and no immunizations. ... [D]iphtheria outbreaks have been described in populations with as much as 94% of the people being previously immunized. These outbreaks, the known importance of carriers in the spread of diphtheria, and the demonstrated failure of toxoid to prevent the carrier state lead us to conclude that the concept of herd immunity is not applicable in the prevention of diphtheria.”)

57. In any event, the incidence of diphtheria in New York in the years prior to and after requiring diphtheria vaccine for school in New York was effectively zero. New York State added vaccination for diphtheria as a requirement for school in 1971, and the law became effective in 1972. (L 1971, ch. 974.) There was one case in all of New York in each year between 1968 and 1970, and no cases in 1971. After requiring the diphtheria vaccine for school, there were three cases in 1972, four cases in 1977, and one case in each of the following years: 1978, 1980, 1983, 1988, 1996, and 2012. Hence, the incidence rate of diphtheria among New York’s 18 million residents has remained essentially zero in the years directly prior to and after making this a required vaccine to attend school under New York State law.

58. I.R. is also already immune to diphtheria. Diphtheria vaccines are licensed based on whether they generate a certain level of antibodies to diphtheria. I.R.'s antibodies levels far exceed the level deemed to confer immunity for licensure of diphtheria vaccines.

59. Diphtheria vaccine is also not without risk, yet Defendants demand that Plaintiff ignore these risks under penalty of being denied a critical government benefit even though there is no benefit to I.R. in engaging in this medical procedure.

60. Hence, compelling the injection of diphtheria vaccine into I.R., against her mother's informed decision and under duress of denying a critical government benefit, including school and the provided disability services, does not pass strict scrutiny.

61. Even under the rational basis test, there is no rational basis to condition a government benefit on injecting a diphtheria vaccine because it does not produce any antibodies to the diphtheria bacteria itself, and hence a vaccinated person can still become infected with and transmit diphtheria bacteria. Furthermore, as applied in this instance I.R. is immune to diphtheria, and therefore the state has no rational basis to require she receive additional protection from the disease.

62. Expelling a child from school is also not the least restrictive means because I.R. is already immune to diphtheria and also because there were effectively no cases of diphtheria before requiring diphtheria vaccine to attend school in New York State, making it clear that preventing diphtheria among school-aged children had already been achieved without needing to expel students in New York State from school for not receiving this product.

63. Conditioning a government benefit upon the injection of a diphtheria vaccine therefore infringes upon the liberty rights to parental choice, bodily integrity, and informed consent

prior to administering a medical procedure, and the substantive due process rights to liberty and to life.

64. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f), which require administration of vaccines and condition a government benefit of attending school and receiving special education services upon injection of diphtheria vaccine that offers personal, not communal protection, should be facially and as applied, struck down for violating the foregoing fundamental rights arising from the Fourteenth Amendment of the United States Constitution.

COUNT IV
42 U.S.C. § 1983
Violation of the Fourteenth Amendment
Conditioning a Public Benefit on the Injection of IPV
Parental Choice, Bodily Integrity, Informed Consent, and Life and Liberty

65. The preceding paragraphs are hereby realleged and incorporated herein by reference.

66. Plaintiff opposes injecting I.R. with IPV when, *inter alia*, there is only risk and no benefit to engaging in this medical procedure because I.R. is already immune to polio and this product only affords personal and not communal protection.

67. IPV is something very different from prior polio vaccines as Sanofi makes clear on the IPV's package insert, including because IPV uses a different biological substrate (which is a large portion of the final product) to grow the virus, has a multi-fold more immunogenic content, uses microcarrier beads, has different final ingredients, produces a different immune system reaction, and its mechanisms of action work differently.

68. New York Public Health Law Section 2164(2)(a) requires that every child receive "an adequate dose or doses of an immunizing agent against ... polio."

69. The compelling state interest to control the spread of infection is absent with regard to IPV which does not prevent becoming infected with and transmitting polio. It only affords potentially personal protection against the symptoms of polio.

70. This is because polio virus proliferates in the intestines and is transmitted through fecal or oral contamination, but IPV generates antibodies in the blood, not in the intestinal tract. *See* WHO, UNICEF, CDC, Polio Global Eradication Initiative, *Inactivated poliovirus vaccine* (“IPV induces very low levels of immunity in the intestine. As a result, when a person immunized with IPV is infected with wild poliovirus, the virus can still multiply inside the intestines and be shed in the feces ... IPV does not stop transmission of the virus.”)

71. In any event, according to the CDC, there were zero cases of polio in New York in 1966, the year *before* the New York State legislature first enacted a requirement to receive the polio vaccine to attend school.

72. I.R. is also already immune to polio. Polio vaccines are licensed based on whether they generate a certain level of antibodies to the polio virus. I.R.’s antibodies levels far exceed the level deemed to confer immunity for licensure of IPV.

73. IPV is also not without risk, yet Defendants demand that Plaintiff ignore these risks under penalty of being denied a critical government benefit even though there is no benefit to I.R. in engaging in this medical procedure.

74. Hence, compelling the injection of IPV into I.R., against her mother’s informed decision and under duress of denying a critical government benefit, including school and the provided disability services, does not pass strict scrutiny.

75. Even under the rational basis test, there is no rational basis to condition a government benefit on injecting IPV because it does not prevent infection and transmission of the

polio virus from person to person. Furthermore, as applied in this instance, I.R. is immune to polio, and therefore the state has no rational basis to require she receive additional protection from the disease.

76. Expelling a child from school is also not the least restrictive means because I.R. is already immune to polio and also because there were no cases of polio in the year before requiring this vaccine to attend school in New York State.

77. Conditioning a government benefit upon the injection of IPV therefore infringes upon the liberty rights to parental choice, bodily integrity, and informed consent prior to administering a medical procedure, and the substantive due process rights to liberty and to life.

78. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f), which require administration of vaccines and condition a government benefit of attending school and receiving special education services upon injection of IPV that offers personal, not communal protection, should be facially and as applied, struck down for violating the foregoing fundamental rights arising from the Fourteenth Amendment of the United States Constitution.

COUNT V

Retaining a Non-Religious Exemption to Vaccination While Eliminating a Religious Exemption Violates the Free Exercise Clause

79. The preceding paragraphs are hereby realleged and incorporated herein by reference.

80. Plaintiff's deeply and sincerely held religious beliefs prevent her from engaging in a medical procedure that:

- a. Violates her free and Informed Conscience, which is an essential teaching of the Catholic Church. Conscience allows Plaintiff to use judgment and discern good from evil in daily life. Plaintiff relies upon the Catechism of the Catholic Church (¶ 1777, 1778, 1782, 1790) which directs that she has a moral obligation to follow

her individual Conscience. This duty is so fundamental in church teaching that Conscience must remain the standard even if individual judgment is in error. Otherwise, her faith would require her to do what she believes is immoral.

- b. Exposes her child to the risks of a procedure without a concomitant benefit. Plaintiff's sincerely held religious beliefs and informed conscience regarding the therapeutic proportionality of the vaccine is supported by the Ethical and Religious Directives for Catholic Health Care Services. This directive clearly states that no person is obligated to submit to a procedure when his or her free and informed Conscience determines that the benefit does not outweigh the risk (§ 32, 56, 57). Plaintiff's faith requires her to assess the risk and benefit of any medical treatment for her child. These directives make it clear that it is her personal judgement, made with a free and informed Conscience, that must determine the therapeutic proportionality of any medical procedure, including vaccination.
- c. Denies her belief in Divine Provenance. Plaintiff, as an intellectual who has studied both science and law, is not free from doubt as to whether God exists or as to the validity of various tenants of the religion she still considers herself a part of. However, it is precisely her study of biology and the amazing intricacies of the human body to heal itself which always bring her back to the belief of divine provenance. It is also what prohibits her from taking the easy route of giving in to the pressures of the State in the face of all that she knows and believes. Two small injections are what separate her daughter from returning to an experience that she loves – going to a school every day that is brimming with other children. However, Plaintiff cannot deny what she knows. She cannot unknow that her daughter is

already immune to the relevant diseases and that another injection of these vaccines may cause her immune system to be unnecessarily disrupted or worse. She cannot unknow that there is no medical benefit to anyone if her daughter received these vaccines. She cannot unknow that her daughter faces only risk, and no benefit, by taking the vaccines. She cannot unknow that she is the *only* guardian of her daughter's health.

81. The United States Constitution guarantees the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to DTaP/Tdap and IPV.

82. The United States Constitution guarantees the fundamental right to free exercise of religion which cannot be infringed upon without a compelling state interest that is implemented in the least restrictive means. As described in preceding paragraphs, which are incorporated herein by reference, the compelling state interest for mandating certain vaccines for school is absent with regard to DTaP/Tdap and IPV.

83. Defendants must provide a religious exemption to vaccination because they provide a non-religious exemption from vaccination—that is, an extremely limited medical exemption. *See, e.g., Fulton v. City of Phila., Pennsylvania*, 141 S. Ct. 1868, 1878 (2021) (“the City may not refuse to extend that [exemption] system to cases of ‘religious hardship’ without compelling reason.” (internal quotations omitted)); *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 537 (1993) (“[I]n circumstances in which individualized exemptions from a general requirement are available, the government may not refuse to extend that system to cases of

‘religious hardship’ without compelling reason.” (internal quotation marks omitted)). *See also Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, 170 F.3d 359, 364 (3rd Cir. 1999) (“[R]efusal to make religious exemptions from its ... policy should be reviewed under strict scrutiny because the Department makes secular exemptions to its policy.”).

84. Wherefore, the portions of PHL 2164 and 10 NYCRR § 66-1.1(f), which require administration of vaccines and condition a government benefit of attending school and receiving special education services upon injection of DTaP/Tdap and IPV should be struck down for failing to provide a religious exemption while providing a non-religious exemption to vaccination and for otherwise violating the free exercise clause, including as applied to Plaintiff.

PRAYER FOR RELIEF

Wherefore, the Plaintiff respectfully requests that this Court:

A. Grant declaratory relief and an injunction prohibiting conditioning the government benefit of attending public school and attended services upon injection of a pertussis vaccine, either generally or as applied to the Plaintiff and I.R.’s circumstances;

B. Grant declaratory relief and an injunction prohibiting conditioning the government benefit of attending public school and attended services upon injection of a tetanus vaccine, either generally or as applied to the Plaintiff and I.R.’s circumstances;

C. Grant declaratory relief and an injunction prohibiting conditioning the government benefit of attending public school and attended services upon injection of a diphtheria vaccine, either generally or as applied to the Plaintiff and I.R.’s circumstances;

D. Grant declaratory relief and an injunction prohibiting conditioning the government benefit of attending public school and attended services upon injection of IPV, either generally or as applied to the Plaintiff and I.R.’s circumstances;

- E. Grant declaratory relief and an injunction prohibiting conditioning the government benefit of attending public school and attended services upon injection of DTaP/Tdap or IPV for failing to provide a religious exemption while providing a non-religious exemption to vaccination and for otherwise violating the free exercise clause, including as applied to Plaintiff;
- F. Award attorneys' fees and costs of this action; and
- G. Grant such further relief as the Court deems necessary and proper.

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